DEC 7 2005

510 (k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510 (k) Contact:	Angela Mikroulis Regulatory Affairs Project Manager Phone: (610) 719-5718 Fax: (610) 719-5102
Trade Name:	Synthes Pangea™ Monoaxial Screws and Hooks
Common / Classification Name:	Spinal interlaminal fixation orthosis; Spinal intervertebral body fixation orthosis; Pedicle screw spinal system
Device Product Code and Classification:	KWP, KWQ, MNH, MNI and NKB 21 CFR § 3050, 21 CFR § 3060, 21 CFR § 3070 Class II and Class III
Predicate:	K031175- SYNTHES Click'X Monoaxial System
Device Description:	The Pangea™ Monoaxial Screws and Hooks are similar to the cleared SYNTHES Click'X Monoaxial System (K031175). Both are components of the Universal Spinal System (USS). Pangea Monoaxial includes dual-core screws and a variety of hook profiles. The Synthes Pangea Monoaxial Screws and Hooks are fabricated from titanium alloy, conforming to ASTM F-1295.

Intended Use/ Indications for Use:	The Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial, Pangea Monoaxial, Dual-Opening and the Small Stature USS (which includes small stature and pediatric patients) are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as a anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion. When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct. When used with the 3.5/6.0 mm parallel connectors, the Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial, Pangea Monoaxial and Dual-Opening USS can be linked to the CerviFix® System. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), the Click'X® Monoaxial, Pangea Monoaxial and Dual-Opening USS Systems. In addition, Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial, Pangea Monoaxial and the Dual-Opening USS can be interchanged with all USS 6.0 mm rods and transconnectors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2007

Ms. Angela Mikroulis
Regulatory Affairs Project Manager
Synthes Spine
1302 Wrights Lane East
West Chester, PA 19380

Re: K052151
Trade Name: Pangea™ Monoaxial Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: December 1, 2005
Received: December 2, 2005

Dear Ms. Mikroulis:

This letter corrects our substantially equivalent letter of December 7, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K052151

Device Name: Synthes Pangea Monoaxial System

Indications for Use:
The Synthes USS (including the Click'X®, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial, Pangea Monoaxial, Dual-Opening and the Small Stature USS (which includes small stature and pediatric patients) are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

When used with the 3.5/6.0-mm parallel connectors, the Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial, and Dual Opening USS can be linked to the Cervifix system. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS, can be linked to the CerviFix System. When used with the 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), the Click'X Monoaxial, Pangea Monoaxial, and Dual Opening USS Systems.

In addition, Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial and the Dual Opening USS can be interchanged with all USS 6.0mm rods and transconnectors.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

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